DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Endo-Therapeutics, Inc.
Mr. Todd Adkisson
1183 Cedar Street
Safety Harbor, FL 34695

JUL 27 2015

Re: K023603
Trade/Device Name: Endo-Glide Guidwire
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY, GCA
Dated (Date on orig SE ltr): January 23, 2003
Received (Date on orig SE ltr): January 27, 2003

Dear Mr. Adkisson,

This letter corrects our substantially equivalent letter of February 19, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K 023603

510(k) INDICATIONS FOR USE STATEMENT

510(k) Number (If KNOWN): K 023603

Device Name: **Endo-Glide Guidewire**

Applicant Name: ***Endo-Therapeutics, Inc***

Indications for Use: Endo-Glide Guidewires are intended to be used for selective cannulization of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts during endoscopic biliary procedures for catheter introduction and exchanges.

Signature: _____ President

Date: 9/2/02

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David G. Hyman
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023603

K023603

510(k) Summary: Endo-Therapeutics Endo-Glide Guidewires

FEB 1 9 2003

(1) Endo-Therapeutics Inc.
1183 Cedar st.
Safety Harbor, FL 34695

Contact Person: Todd Adkisson
Date Prepared: 9/2/02

510(k) #: K

(2) **Trade or Proprietary Name:** Endo-Glide Guidewire

Common Name: Guidewire

Classified Name: Gastrointestinal Guidewire

(3) **Equivalent Predicate Devices:**
Jagwire™ Guidewire (K922302),
Flex Finder® Guidewire (K964955),
Next Generation Guidewire (K011759)

(4) **Description of Device:**
The Endo-Glide Guidewire has a range of diameters from 0.025" to 0.035" and lengths from 250cm to 450cm. The wires are offered with and without a 50mm radiopaque platinum distal tip (curved and straight). The wires are assembled with a solid nitinol or stainless steel core wire, which can be tapered at the distal tip. A lubricious coating (PTFE or hydrophilic) surrounds the entire core and/or tip, which also provides insulation.

(5) **Intended Use:**
Endo-Glide Guidewire is used for selective cannulization of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts during endoscopic biliary procedures for catheter introduction and exchanges.

(6) **Technological Characteristics:**
The Endo-Therapeutics Endo-Glide Guidewires have essentially the same technological characteristics as the predicate device. The intended use, design, materials and method of operation are all substantially similar to the before mentioned guidewires.